

WHAT IS CLAIMED IS:

1. A method for determining the total amount of gastrin hormone in a biological fluid sample, comprising the steps of:

- (a) obtaining a biological fluid sample comprising gastrin hormone from a patient;
- (b) providing an immobilized antibody that selectively binds a C-terminal epitope of the gastrin hormone;
- (c) incubating the sample in the presence of an N-terminal sequence gastrin peptide under suitable conditions for binding of the gastrin hormone in the sample to said antibody to produce an immobilized complex of said antibody bound to the gastrin hormone;
- (d) washing the immobilized complex to remove N-terminal sequence gastrin peptide, and incubating the complex with a suitable detectable marker-conjugated antibody that selectively binds an N-terminal epitope of gastrin hormone to form an immobilized detectable marker-conjugated antibody complex;
- (e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and
- (f) measuring the developed reagent to determine the total amount of the gastrin hormone in the biological fluid sample.

2. The method of claim 1, wherein the gastrin hormone is G17, or G34 and wherein the C-terminal selective antibody selectively binds the C-terminal of G17 or the C-terminal of G34.

3. The method of claim 2, wherein the C-terminal selective antibody that selectively binds the C-terminal end of G17 or G34 is a monoclonal antibody.

4. The method of claim 3, wherein the monoclonal antibody selectively binds the C-terminal end of G17 or G34 and has the characteristics of the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).

5. The method of claim 4, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).

6. The method of claim 2, wherein the N-terminal selective antibody is selective for the N-terminal of G17.

7. The method of claim 6, wherein the N-terminal selective antibody is a monoclonal antibody.

8. The method of claim 7, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

9. The method of claim 8, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

10. The method of claim 2, wherein the N-terminal selective antibody is selective for the N-terminal of G34.

11. The method of claim 10, wherein the N-terminal selective antibody is a monoclonal antibody.

12. The method of claim 11, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).

13. The method of claim 12, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).

14. A method for determining the amount of free gastrin hormone in a biological fluid sample, comprising the steps of:

- (a) obtaining a biological fluid sample comprising a gastrin hormone from a patient;
- (b) providing an immobilized antibody that selectively binds a N-terminal epitope of the gastrin hormone;
- (c) incubating the sample under suitable conditions for binding of the gastrin hormone in the sample to said antibody to produce an immobilized complex of said antibody bound to the gastrin hormone;

(d) washing the immobilized complex to remove unbound antibody, and reacting the complex with a suitable detectable marker-conjugated antibody that selectively binds an C-terminal epitope bound to the gastrin hormone;

(e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and

(f) measuring the developed reagent to determine the amount of free gastrin hormone in the biological fluid sample.

15. The method of claim 14, wherein the gastrin hormone is G17, or G34 and wherein the C-terminal selective antibody selectively binds the C-terminal of G17 or the C-terminal of G34.

16. The method of claim 15, wherein the C-terminal selective antibody that selectively binds the C-terminal end of G17 or G34 is a monoclonal antibody.

17. The method of claim 16, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).

18. The method of claim 17, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).

19. The method of claim 15, wherein the N-terminal selective antibody is selective for the N-terminal of G17.

20. The method of claim 19, wherein the N-terminal selective antibody is a monoclonal antibody.

21. The method of claim 20, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

22. The method of claim 21, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

23. The method of claim 14, wherein the N-terminal selective antibody is selective for the N-terminal of G34.

24. The method of claim 23, wherein the N-terminal selective antibody is a monoclonal antibody.

25. The method of claim 24, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).

26. The method of claim 24, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).

27. The method of claim 1 or claim 14, wherein the gastrin hormone is Gly-extended G17, or Gly-extended G34 and wherein the C-terminal selective antibody selectively binds the C-terminal of Gly-extended G17 or Gly-extended G34.

28. The method of claim 27, wherein the C-terminal selective antibody that selectively binds the C-terminal end of Gly-extended G17 or Gly-extended G34 is a monoclonal antibody.

29. The method of claim 28, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 445-1 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 445-2 (ATCC accession #).

30. The method of claim 29, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 445-1 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 445-2 (ATCC accession #).

31. The method of claim 14, wherein the N-terminal selective antibody is selective for the N-terminal of G17 or Gly-extended G17.

32. The method of claim 31, wherein the antibody selective for the N-terminal of Gly-extended G17 or G17 is a monoclonal antibody.

33. The method of claim 32, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

34. The method of claim 33, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession #).

35. The method of claim 14, wherein the N-terminal selective antibody is selective for the N-terminal of G34 or Gly-extended G34.

36. The method of claim 35, wherein the antibody selective for the N-terminal of Gly-extended G34 or G34 is a monoclonal antibody.

37. The method of claim 36, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).

38. A method for determining the total amount of bound plus free peptide in a biological fluid sample, wherein at least a portion of the peptide is reversibly-bound at a first binding sequence, the method comprising:

- (a) obtaining a biological fluid sample comprising the peptide;
- (b) providing a solid substrate coated with an antibody that selectively binds a first epitope of the peptide which is not present in the first binding sequence;
- (c) incubating the sample in the presence of a fragment of the peptide comprising the first binding sequence, but not the first epitope, under suitable conditions for binding of the peptide to said antibody to produce an immobilized complex of said antibody bound to the peptide;
- (d) washing the immobilized complex to remove unbound antibody and the fragment of the peptide, and reacting the complex with a suitable detectable marker-conjugated antibody that selectively binds a second epitope of the peptide;
- (e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and
- (f) measuring the developed reagent to determine the total amount of bound plus free peptide in the biological fluid sample.

39. A method of evaluating a gastrin hormone-blocking treatment of a patient suffering from a gastrin hormone-mediated disease or condition, comprising the steps of:
- a) obtaining a first sample of biological fluid from the patient prior to or in the early stages of the treatment;
 - b) determining the level of gastrin hormone in the first sample by an immunoassay method;
 - c) performing a diagnosis on the basis of the disease or condition to be treated and the level of gastrin hormone in the first sample;
 - d) administering the treatment to the patient, comprising: a first agent or a substance that generates a first agent which binds gastrin hormone so as to modulate its binding to its target receptor *in vivo*;
 - e) obtaining a second sample of biological fluid from the patient after a suitable time within which the treatment would have an effect;
 - f) determining the level of total gastrin hormone including bound and free gastrin hormone in a first aliquot of the second sample by an immunoassay, wherein the first aliquot of the second sample is incubated with (i) a second agent that displaces any gastrin hormone bound by the first agent, and (ii) an immobilized anti-gastrin hormone antibody, wherein the immobilized antibody does not bind the second agent; washing to remove the second agent and adding a detectable antibody that binds the gastrin hormone and does not compete with the immobilized antibody, forming an immunocomplex comprising the immobilized antibody bound to gastrin hormone, the gastrin hormone being bound by the detectable antibody;
 - g) detecting the amount of the detectable antibody in the immunocomplex and thereby determining the amount of total gastrin hormone in the second sample;
 - h) determining the level of free gastrin hormone by repeating steps f) and g) with a second aliquot of the second sample, wherein the incubation in step f) is performed without the second agent; and
 - j) comparing the determined amounts of free gastrin hormone in the first sample with the amounts of free and total gastrin hormone in the second sample so as to determine the efficacy of the gastrin-blocking treatment in the patient.
40. The method of claim 39, wherein the biological fluid is serum.

41. The method of claim 39, wherein the first agent is an antibody to the N-terminus of G17, or a G17 receptor mimic, and the second agent is an N-terminal G17 peptide.
42. The method of claim 41, the substance that generates the first agent is a conjugate comprising a first N-terminal G17 peptide.
43. The method of claim 41, wherein the immobilized antibody binds the C-terminus of G17.
44. The method of claim 43, wherein the immobilized antibody that binds the C-terminus of G17 is a monoclonal antibody.
45. The method of claim 44, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).
46. The method of claim 45, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).
47. The method of claim 41, wherein the detectable antibody binds the N-terminus of G17.
48. The method of claim 47, wherein the antibody selective for the N-terminal of G17 is a monoclonal antibody.
49. The method of claim 48, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) and hybridoma 400-4 (ATCC accession #).
50. The method of claim 49, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 400-1 (ATCC accession #), hybridoma 400-2 (ATCC accession #), hybridoma 400-3 (ATCC accession #) and hybridoma 400-4 (ATCC accession #).
51. The method of claim 39, wherein the first agent is an antibody to the N-terminal of G34, or a G34 receptor mimic, and the second agent is an N-terminal G34 peptide.
52. The method of claim 51, wherein the substance that generates the first agent is a conjugate comprising a first N-terminal G34 peptide.
53. The method of claim 51, wherein the immobilized antibody binds the C-terminus of G34.

54. The method of claim 53, wherein the immobilized antibody that binds the C-terminus of G34 is a monoclonal antibody.
55. The method of claim 54, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).
56. The method of claim 55, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession #).
57. The method of claim 51, wherein the detectable antibody binds the N-terminus of G34.
58. The method of claim 57, wherein the antibody that binds the N-terminus of G34 is a monoclonal antibody.
59. The method of claim 58, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 401-2 (ATCC accession #).
60. The method of claim 59, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).
61. The method of claim 38, wherein the first agent is an antibody to the N-terminal of G17-Gly, or a G17-Gly receptor mimic, and the second agent is an N-terminal G17 peptide.
62. The method of claim 61, wherein the substance that generates the first agent is a conjugate comprising a first N-terminal G17 peptide.
63. The method of claim 61, wherein the immobilized antibody binds the N-terminus of G17.
64. The method of claim 63, wherein the immobilized antibody that binds the N-terminus of G17 is a monoclonal antibody.
65. The method of claim 64, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma selected from the group consisting of the hybridoma 400-1 (ATCC accession #), the hybridoma 400-2 (ATCC accession #), the hybridoma 400-3 and the hybridoma 400-4 (ATCC accession #).
66. The method of claim 65, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma selected from the group consisting of the hybridoma 400-1

(ATCC accession #), the hybridoma 400-2 (ATCC accession #), the hybridoma 400-3 and the hybridoma 400-4 (ATCC accession #) (ATCC accession #).

67. The method of claim 61, wherein the detectable antibody binds the C-terminus of G17-Gly.
68. The method of claim 67, wherein the antibody that binds the C-terminus of G17-Gly is a monoclonal antibody.
69. The method of claim 68, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 445-1 (ATCC accession #) and hybridoma 445-2 (ATCC accession #).
70. The method of claim 69, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 445-1 (ATCC accession #) and hybridoma 445-2 (ATCC accession #).
71. The method of claim 39, wherein the first agent is an antibody to the N-terminal of G34-Gly, or a G34-Gly receptor mimic, and the second agent is an N-terminal G34 peptide.
72. The method of claim 71, wherein the substance that generates the first agent is a conjugate comprising a first N-terminal G34 peptide.
73. The method of claim 71, wherein the immobilized antibody binds the N-terminus of G34.
74. The method of claim 73, wherein the immobilized antibody that binds the N-terminus of G34 is a monoclonal antibody.
75. The method of claim 74, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #).
76. The method of claim 75, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession #) (ATCC accession #).
77. The method of claim 71, wherein the detectable antibody binds the C-terminus of G34-Gly.
78. The method of claim 77, wherein the antibody that binds the C-terminus of G34-Gly is a monoclonal antibody.

79. The method of claim 78, wherein the monoclonal antibody has the characteristics of the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 445-1 (ATCC accession #) and hybridoma 445-2 (ATCC accession #).
80. The method of claim 79, wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma selected from the group consisting of hybridoma 445-1 (ATCC accession #) and hybridoma 445-2 (ATCC accession #).